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EXAMINER

MORAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/267,199

Applicant(s)

BHAT ET AL.

Examiner

Morjorie Moran

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: See Continuation Sheet.

All rejections and objections not repeated below are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

Claims 3-9 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6, filed 9/14/00.

An action on the merits of elected claims 1-2 and 10-22 follows.

35 U.S.C. 101/112 Utility Rejections

Claim 2 is again rejected, and claims 10-22 are newly rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or by a well established utility.

Applicant's arguments filed 3/19/01 have been fully considered but they are not persuasive.

Applicant argues that the claimed nucleic acids are useful for obtaining other nucleic acids from the same species, for obtaining homologous nucleic acids from other species, for obtaining promoter sequences and other genetic elements, for determining the presence and/or identity of polymorphisms, for measuring mRNA in a sample, and for acting as probes or markers. Applicant further cites 20 USPQ2d 1094, 1100 (Fed. Cir. 1991) as support for the argument that argues that the examiner's allegation that "the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" is wrong. In response, it is noted the specification teaches only general uses (purposes), but does not teach any specific "purpose" for the claimed SEQ ID NO's. The uses argued above are ones which are applicable to the general class of nucleic acids and are not specific to the SEQ ID NO's claimed. It is well known in the art that polynucleotides, including others than those recited in the instant claims, can be used in hybridization assays to obtain other (e.g. homologous or complementary) nucleic acid sequences, to identify polymorphisms, etc. A nucleic acid molecule may have utility based on its use as a marker or probe for or related to a specific disease condition (e.g. probes for Huntington's chorea, cystic fibrosis, etc.); however, no

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correlation between a claimed SEQ ID NO: and a specific disease condition is taught by the instant specification. With regard to the case cited on page 8 of the response, it is noted that utility is question was for a single part of a measuring device. As the device as a whole was deemed to have utility (which was not in question), the mounting means recited in the appealed claim was also deemed to have utility. The art in question in the cited case is not analogous to nucleic acids, and the fact pattern is not the same as that found in the instant application (i.e. applicant is not arguing utility for a "part" of a sequence), therefore the argument regarding the "best or only way to achieve a result" is not considered relevant. For these reasons, the general utilities taught by the specification and argued by applicant do not constitute a specific, substantial, and credible utility for the claimed SEQ ID NO's.

Applicant further argues that the claimed nucleic acid molecules are useful to identify a unique subset of related sequences, wherein the subset can not be identified by any generic nucleic acid molecule. It is admitted that a unique nucleic acid sequence may be used to identify a unique subset of related sequences. However, as the utility for the "original" nucleic acid sequence is unknown, the unique subset itself has no known utility. As set forth above, use of a nucleic acid sequence to identify other (related) sequences correlated to a known disease condition would confer utility to the probing sequence; however, no such correlation is taught for the claimed SEQ ID NO's. Merely using a sequence with no known utility to identify other sequences, which themselves do not have utility, does not confer utility upon the "first" sequence, therefore a use to identify a "unique" subset of related sequences is not a specific, substantial, and credible utility for the claimed SEQ ID NO's.

On pages 7 and 8 of the response, applicants argue that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. However, the fact situation in the instant application is not analogous to applicants' microscope or golf club examples. Applicant further argues that credibility was not assessed in the office action of 3/19/01. In response, it should be noted that if an invention does not have a specific and substantial utility, then it does not have a credible utility, therefore credibility was not assessed as a separate issue. Applicant cites several court cases in the argument regarding credibility. With regard to *In re Ziegler* (20 USPQ2d 1600, 1603), it is noted that the court decided that "Ziegler did not disclose any practical use for the

polypropylene or its film". Again, this fact pattern is different from that of the instant application. With regard to *In re Brana* (34 USPQ2d 1436, 1441), the utility of Brana's compounds was based on the activity of the claimed compounds against lymphocytic leukemia, as compared to known compounds with similar activity. Applicant should note that Brana's compounds had established activity (as shown in examples) against a known disease. Similarly, in *Cross vs. Iizuka* (224 USPQ 739, 742), the compounds claimed were shown to have enzyme inhibitory activity related to a known therapeutic use. The instant specification does not disclose any correlation between nucleic acid sequences recited in the instant claims and a known disease, therefore the SEQ ID NO's recited in the instant claims can not be said to have utility for the same reasons given in the Brana or Cross vs. Iizuka cases. While the examiner must treat as true any statement of fact made by an applicant unless countervailing evidence can be provided, as argued by applicant on page 9 of the response, no statements regarding a "practical" utility, other than those already addressed above, have been made by applicant with regard to the claimed nucleic acid sequences.

A nucleic acid sequence may have utility based on a protein encoded by the nucleic acid sequence if the protein itself has a specific, substantial, and credible utility, or a well established utility. For example, a protein kinase has a well established utility, therefore a nucleic acid encoding a protein kinase has utility. The specification alleges, and applicant argues in the response filed 3/19/01, that the claimed nucleic acid sequences encode various enzymes involved in a tocopherol synthesis pathway. Applicant further points to Table A wherein peptide sequences putatively encoded by applicants' nucleic acid sequences are compared to protein sequences of known proteins. Nowhere does the specification disclose that the claimed nucleic acid sequences actually encode the enzymes disclosed in Table A. It is noted that while sequence homology may be indicative that a protein is encoded, homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence. See p. 7 of the office action of 11/21/00 regarding lack of predictability based on sequence homology. In fact, the instant specification does not teach anywhere that any peptide or protein is actually encoded by or produced from the disclosed nucleic acid sequences. The specification does not disclose open reading frames, start and stop codons, or any other information for any sequence which would indicate that the nucleic acid sequences enclosed actually encode a protein or that a functional protein or peptide sequence can be transcribed and translated from the

polynucleotide sequences. The prior art does not teach that the elected SEQ ID's encode the alleged proteins. In addition, while it is possible that at least some of the claimed sequences may encode a protein, the specification does not show, by example or otherwise, that the protein, in each case, is actually the enzyme disclosed as being homologous to the peptide putatively encoded; e.g. by an activity assay, antibody recognition, etc. It is noted that working examples are not necessary, but are helpful when other evidence for utility is absent. As the instant specification does not disclose, and the prior art does not teach, that the instantly claimed nucleic acid sequences actually encode any protein or peptide, specifically the enzymes recited in Table A, the nucleic acid sequences represented by SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232 do not have utility based on utility of a protein encoded thereby.

For all of the reasons set forth above, the rejection of claim 2 is maintained and new claims 10-22 are rejected.

Claims 2 and 10-22 are also rejected under 35 U.S.C. 112, first paragraph for not being enabled.

Applicant's arguments filed 3/16/01 have been fully considered but they are not persuasive. Applicant argues that as the claimed nucleic acid sequences have utility, they are enabled. This enablement rejection is linked to the utility rejection, as previously set forth. As the utility rejection is maintained, the enablement rejection is also maintained. Arguments set forth on page 10 of the response with regard to this enablement rejection will be held in abeyance until the utility rejection is overcome.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 1-2 are again rejected, and new claims 12-21 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 3/16/01 have been fully considered but they are not persuasive. Applicant argues that he was in possession of the claimed nucleic acids sequences and points to Table A as (apparent) evidence that these sequences encode the claimed enzymes. In response, it is noted, as previously set forth and reiterated above, that the instant specification does not teach that any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232 actually encode any protein or peptide, specifically the enzymes recited in claims 1 and 12-21. Again, it is noted that homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence. With regard to Table A, the highest percent homology shown between any peptide putatively encoded by one of the claimed sequences and a known protein is 81% (for the peptide putatively encoded by SEQ ID NO: 232), while the lowest shown is 40% (for the peptide putatively encoded by SEQ ID NO: 147). While 80% certainly represents a peptide which would reasonably be expected to be related to the known protein (e.g. by having one or more structural motifs in common), it is not evidence that an enzyme with chorismate synthase activity is actually encoded by and translated from the SEQ ID NO: 232. One of skill in the art would reasonably doubt whether a peptide which is only 40% homologous to another is indeed a protein with similar activity. It is noted that in some cases, nucleic acids which encode peptides with higher % homology to known proteins are disclosed in Table A (e.g. SEQ ID NO: 2 putatively encodes a peptide with 93% homology to a synthase whereas elected SEQ ID NO: 1 putatively encodes a peptide with only 77% homology); however, these nucleic acid sequences are not among those elected in response to the restriction requirement. In addition, none of the SEQ ID NO's elected are disclosed as putatively encoding peptides homologous to the proteins recited in groups (j)-(p) of claim 1. While the nucleic acid sequences represented by the claimed SEQ ID NO's are fully described by the specification at the time of filing, nucleic acid sequences *encoding the proteins* recited in claims 1 and 12-22 were not fully described as set forth above. The specification does not disclose that the claimed nucleic acid sequences actually encode any proteins or peptides, therefore nucleic acid sequences encoding the claimed proteins AND comprising the claimed SEQ ID NO's were not described in the specification as originally filed. For the reasons set forth above, the rejection of claims 1-2 is maintained and claims 12-21 are rejected.

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Claims 1-2 and 10-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

The specification discloses SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232. The specific sequences corresponding to SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232 meet the written description provisions of 35 USC 112, first paragraph. However, claims 2 and 10-22 recite open claim language (i.e. comprising, comprises, or having) and are therefore also directed to encompass gene sequences, sequences that hybridize SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232, corresponding sequences from other species, derivatives, allelic variants, splice variants, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims.

With regard to claim 1, the specification discloses on pages 2-11 that the various enzymes recited in the claims are known and have been isolated from various sources. Page 7 of the specification discloses that the gene encoding hydroxyphenylpyruvate dioxygenase has been identified, but does not disclose the source of the gene. Page 8 discloses that the gene for geranylgeranyl-pyrophosphate synthase has been isolated from Arabidopsis and C. roseus. The specification does not disclose nucleic acid sequences encoding any of the maize or soybean enzymes recited in claim 1, as set forth above. The prior art teaches several nucleic acid sequences encoding maize or soybean enzymes, as set forth below; however, these sequences are not recited in the instant specification nor are the references teaching them incorporated by reference. Neither the prior art nor the instant specification teach nucleic acid sequences encoding the proteins designated as (b)-(e), (g), and (i)-(o), therefore nucleic acids encoding these proteins are not described at all. No amino acid sequences are taught in the instant specification. Claim 1 is directed to encompass many variants, mutations, deleted sequences, etc. as long as those sequences encode one of the recited proteins. As it is unknown how many or what variants may exist for each of the recited proteins, one skilled in the art would not be able to envision all of the embodiments represented by claim 1. The specification fails to provide sufficient written description to support the limitations of the claim.

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Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the specific sequences corresponding to SEQ ID NO's 308, 727, 1169, 1254, 1616, 2128, 2535, 3081, 3769, or 5748, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent

pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only polynucleotide sequences consisting of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim 2 is again rejected and new claims 12-21 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

Applicant's arguments filed 3/16/01 have been fully considered but they are not persuasive. In response to applicant's argument Table A discloses that the claimed nucleic acid sequences encode the proteins claimed, it is again noted that homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence, and that the instant specification does not disclose anywhere that the claimed nucleic acids actually encode any peptide or protein, as previously set forth and reiterated above. Also as previously set forth, while the prior art teaches isolated nucleic acid sequences which encode the corn or soybean enzymes recited in the claims, the sequences taught by the prior art are not the same as those recited in the instant claims. Given a specified open reading frame, one skilled in the art would certainly know how to synthesis a peptide from a specified sequence. However, the instant specification merely discloses sequences, without any information as to open reading frames, start and stop codons, etc. It is known in the art that nucleic acids (genes) from eukaryotic

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organisms often comprise multiple open reading frames, (i.e. multiple start and/or stop codons), therefore one skilled in the art must determine, for any given sequence, which open reading frame to use to generate a peptide. Given an amino acid sequence for a particular peptide, it would require fairly routine experimentation to "line up" the encoding polynucleotide with the peptide sequence to determine which portion of the nucleic acid sequence comprises the coding region for the peptide. The instant specification does not disclose any amino acid sequences. As no information which would allow one skilled in the art to determine how to generate the specific peptides used for the homology comparisons of Table A is supplied by the instant specification, it would require undue experimentation for one skilled in the art to determine how to generate the putative peptides from the disclosed nucleic acid sequences. The specification does not set forth any methods or assays for determining whether a specific enzyme has been produced, therefore it would require undue experimentation for one skilled in the art to determine if a particular peptide synthesized from any of the disclosed nucleic acid sequences is the enzyme recited. For example, while assays to determine kinase activity are known in the art, each is specific to a particular substrate. An assay to detect tyrosine kinase activity would not necessarily detect shikimate kinase activity, therefore one skilled in the art would have to develop an assay to determine if the desired kinase was indeed produced. The specification discloses that BLASTX was used to determine homology of putatively encoded peptides to known proteins; however, the parameters for generating such homology information is not disclosed. Table A does not disclose which databases (i.e. organisms, sequence parameters, etc.) were used to generate the homology information shown, therefore one skilled in the art would be at a loss to know whether the whole of a particular sequence, or only a part thereof, comprises a particular coding region which results in the stated homology. In addition, as the parameters and comparative databases are not disclosed, one skilled in the art would not know how to determine if the peptide produced from a particular nucleic acid sequence is the same as the one used by applicants to generate the homology information in Table A. The level of skill in the art is acknowledged to be high. As previously set forth, sequences encoding some of the maize or soybean proteins set forth in claim 1 are known in the art; however, these are not the sequences recited in the claims. One skilled in the art would therefore (a) have to determine which portion of a particular SEQ ID NO: encodes a specific protein, (b) determine if the protein produced is the same as that recited in Table A (e.g. determine if the homology "matches" that

disclosed), (c) determine whether the protein produced is the enzyme recited in the claims. As the one skilled in the art must "guess" at some information (e.g. open reading frames, homology parameters) and/or develop new assays to arrive at the claimed invention, it would require undue experimentation for one skilled in the art to know how to make and use the claimed invention.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 11 -21 recites "said nucleic acid molecule" in lines 1-2. Claims 12-21 also recite "said nucleic acid molecule" in lines 2-3. Line 1 of each of claims 11-21 and line 1 of parent claim 10 recites an "isolated nucleic acid molecule". Parent claim 10 also recites a "nucleic acid molecule" in lines 3-4. It is unclear whether the antecedent basis for "said nucleic acid molecule" of claims 11-21 is intended to be the isolated nucleic acid molecule recited in line 1 of each claim, or is intended to be the nucleic acid molecule to which the isolated one hybridizes, as set forth in parent claim 10, therefore claims 11-21 are indefinite. For purpose of applying the prior art, the antecedent basis for every "said nucleic acid molecule" in claims 11-21 is interpreted to be the isolated nucleic acid molecule first recited in line 1 of claim 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is again rejected, as previously set forth in the office action of 11/21/00, and new claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by EICHHOLTZ *et al.* (WO 92/06201).

Applicant's arguments filed 3/16/01 have been fully considered but they are not persuasive. In response to applicant's argument that EICHHOLTZ teaches only an amino acid sequence and does not specifically teach a nucleic acid sequence, it is noted that EICHHOLTZ teaches on page 64, lines 20-27, "a coding sequence which encodes for a glycoprophosphate tolerant form of maize EPSP synthase" which is produced by mutating a specific sequence/vector (pMON9951) to produce another specific sequence/vector (pMON9960). Instant claim 1 recites "a substantially purified nucleic acid sequence that encodes a maize or soybean tocopherol synthesis pathway enzyme" wherein the enzyme is selected from a list including EPSP synthase (designated as (h) in instant claim 1). Instant claim 1 does not recite any specific nucleic acid sequences encoding the enzymes recited therein. EICHHOLTZ clearly describes at least two isolated (i.e. "substantially purified") nucleic acid molecules comprising sequences encoding maize EPSP synthase, as previously set forth and further clarified above, therefore the examiner maintains that EICHHOLTZ anticipates claim 1.

The sequence encoding the EPSP synthase of EICHHOLTZ is 98.8% identical to instant SEQ ID NO: 184 and would be expected to hybridize to a complement of SEQ ID NO: 184 under the conditions set forth in instant claim 10, therefore claim 10 is also anticipated.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by BROWN *et al.* (US 5,859,347).

Applicant's arguments filed 3/16/01 have been fully considered but they are not persuasive. In response to applicant's argument that BROWN teaches only an amino acid sequence and does not specifically teach a nucleic acid sequence, it is noted that BROWN teaches, in column 22, lines 59-63, a vector containing an EPSPS gene and teaches a restriction fragment "containing the maize EPSPS coding sequence". As set forth above, claim 1 recites only nucleic acids encoding particular enzymes, but does not limit the nucleic acids to specific sequences. As BROWN teaches a substantially purified (isolated) nucleic acid

sequence encoding maize EPSPS, as previously set forth and clarified above, the examiner maintains that BROWN anticipates claim 1.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by BAYSDORFER (Genbank accession no. AA661448, 11/12/1997).

BAYSDORFER teaches an mRNA sequence from maize encoding 3-deoxy-d-arabino-heptulosonate 7-phosphate synthase, thereby anticipating claim 1. BAYSDORFER's sequence is an mRNA with complementarity to instant SEQ ID NO: 1, and would be expected to hybridize to SEQ ID NO: 1 under the conditions recited in instant claim 10, therefore claim 10 is also anticipated.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by SASAKI (Genbank accession no. D39938, 11/11/1994).

SASAKI teaches a cDNA sequence which is 87.7% identical to instant SEQ ID NO: 1, and would be expected to hybridize under the conditions recited in instant claim 10 to a complement of SE QID NO: 1, therefore claim 10 is anticipated.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by BONNER et al. (Biochem. J. (1994) vol. 302, pages 11-14).

BONNER teaches a cDNA encoding shikimate dehydrogenase (abstract). BONNER's cDNA is 75% identical to SEQ ID NO: 158 and would be expected to hybridize under the conditions recited in instant SEQ IDNO: 10 to a complement of instant SEQ ID NO: 158, therefore claim 10 is anticipated.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by LEBRUN et al. (Genbank accession no. X63374, 9/4/1996).

LEBRUN teaches a nucleic acid sequence encoding EPSP synthase in maize, thereby anticipating claim 1. LEBRUN's sequence is 80% identical to instant SEQ ID NO: 184 and would be expected to hybridize to a complement of SEQ ID NO: 184 under the conditions recited in instant claim 10, therefore claim 10 is also anticipated.

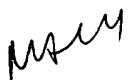
Conclusion

Claims 1-2 and 10-22 are rejected. Claims 3-9 are withdrawn. Claims 2 and 11-22 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.



Marjorie A. Moran
June 4, 2001



MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600

Continuation of 20. Other: detailed action / (3) NCBI Sequence Viewer Sheets.